

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION**

**ALICIA SMITH, CAROLINA BOURQUE,
EMMA BURKEY, CHRISTOPHER CODY
FLINT, MICHELLE ZIMMERMAN, PhD,
ERIN RHODES, and JESSICA KROGMEIER,
LORIN JEPPSEN, and REACT19, INC**

Plaintiffs,

-vs.-

**UNITED STATES OF AMERICA, UNITED
STATES HEALTH RESOURCES AND
SERVICES ADMINISTRATION, UNITED
STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES, and JOHN DOES 1-3,**

Defendants.

Case No. 3:23-cv-01425-EEF-KDM

Judge Elizabeth E. Foote

Magistrate Kayla D. McClusky

**THIRD AMENDED VERIFIED COMPLAINT FOR
DECLARATORY RELIEF**

INTRODUCTION

1. This case presents the heartbreaking plights of a cross-section of ordinary Americans who suffered and continue to suffer devastating and debilitating injuries which started within days of receiving a COVID-19 vaccine. While drugmakers reap billions of dollars in profits behind the impenetrable shield of legal immunity, Plaintiffs and their families are left with shattered lives, mounting medical bills, ongoing testing and treatment, and in some cases, permanent disabilities and death. The Court should be aware that for every story told in this case, there are thousands upon thousands more, equally heartbreaking and unjust.

2. Plaintiffs desire to bring common law and state law claims for, *inter alia*, negligence, intentional infliction of emotional distress (“**IIED**”), and products liability against the manufacturers and administrators of the products that injured them.¹

3. Instead of being able to sue the vaccine manufacturers for their injuries in a court of law, Plaintiffs have been forced by federal statute, the PREP Act, into the Countermeasures Injury Compensation Program (“**CICP**”). The CICP is akin to a black hole into which Plaintiffs submit a request for benefits, then wait an indeterminate amount of time for a decision, and for those who have received any decision, are ultimately wholly denied. Plaintiffs have no access to judicial review and are left to cope with their physical injuries and all resulting financial, emotional, and mental injuries.

4. Carolina Bourque used to travel extensively in her role with the Louisiana Department of Wildlife and Fisheries. Carolina loved to travel and hike, and she was always ready

¹ It is Plaintiffs expectation that, pursuant to the instant litigation, the statutes of limitation on these claims will be tolled. Plaintiffs have not initiated these suits, bringing common law and state claims, because to do so would be futile pursuant to the PREP Act and Plaintiffs need not engage in futile behavior to garner standing. *See J.R. v. Austin Indep. Sch. Dist.*, 574 F. Supp. 3d 428, 435 (W.D. Tex. 2021).

for an adventure. After receiving the Moderna vaccine, she can no longer complete basic daily tasks, travel, or even drive.

5. Emma Burkey, a healthy Nevada high school student, suffered blood clots in her brain and seizures less than two weeks after receiving the Johnson & Johnson (“J&J”) vaccine. After three brain surgeries and thousands of hours of physical therapy, she struggles to walk, write, and care for herself. Her youth, as she knew it, is over. Her parents, who were on the verge of retirement, now work around the clock beneath mounting debt, with the somber reality that Emma cannot possibly care for herself.

6. Cody Flint, a husband, father, and pilot from Mississippi with over 10,000 flight hours, suffered immediate adverse reactions to the Pfizer vaccine, culminating in vertigo and ruptured inner ears two days later which nearly resulted in a deadly plane crash. Cody will never fly again because he cannot possibly afford all the treatment needed to repair his injuries. His family is *“flat broke, swamped in debt, and has no real path forward.”*

7. Michelle Zimmerman, PhD, a highly educated K-12 worker in Washington, suffered severe adverse events after she received the J&J vaccine to comply with federal guidelines and to set a positive example for her students. She is now medically disabled, suffering from a severe brain injury, and unable to work, drive, or walk for more than a few minutes at a time. In Michelle’s words: *“I have had everything that I love stripped from me.”*

8. Jessica Krogmeier, a mother, registered nurse, and respiratory therapist from Iowa, received the Pfizer vaccine to comply with requirements for her profession. She used to dream of furthering her education and advancing into nursing leadership. Now, she cannot work full time because of her ongoing symptoms. Jessica used to be hopeful about the future, but her life has

dramatically changed: *“I have no idea how it will feel day to day. I don’t even think I will live to see my kid graduate.”*

9. Despite their grievous injuries and the catastrophic effects on their lives, the only relief afforded to these Americans who “did the right thing” and got a COVID-19 vaccine is potential limited compensation under CICP. The federal law that created the CICP immunizes vaccine manufacturers and administrators from financial liability and, in so doing, it removes the ability to bring common law and state law claims against them.² In exchange, CICP is supposed to compensate those who are injured by “covered countermeasures” like the COVID-19 vaccine.³ The purported purpose of CICP is to “provid[e] **timely, uniform, and adequate compensation** to eligible individuals for covered injuries and severe adverse events directly caused by the administration or use of a covered countermeasure”;⁴ however, as detailed herein, CICP is akin to a Potemkin village; it is an elaborate façade designed to hide an undesirable reality. CICP is the

² The only exception is for “willful misconduct.” If a willful misconduct claim could be brought by the U.S. government under the Public Health Service Act or the Food, Drug, and Cosmetic Act, then a plaintiff cannot bring that claim unless the U.S. government does so first. For other willful misconduct claims, a plaintiff must satisfy an extremely high burden of proof, especially against a vaccine manufacturer. Notably, willful misconduct first requires that the plaintiff seek compensation through the CICP and so the program is inescapable. If a plaintiff’s request is granted, he or she cannot sue for willful misconduct if he or she elects to receive that compensation. If the plaintiff chooses instead to file a lawsuit, injured persons may sue only in the U.S. District Court for the District of Columbia. Such lawsuits must meet heightened standards for pleading and discovery and are subject to procedural provisions generally favorable to defendants. Injured persons must prove willful misconduct by clear and convincing evidence (a higher standard than in a typical civil case), and recovery for noneconomic damages such as pain and suffering is limited. A plaintiff must show that a defendant acted (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. 42 U.S.C. §§ 247d-6d(c)(1)(A), (c)(3), (e)(1).

³ CICP covers numerous “countermeasures,” a category which includes more than COVID-19 vaccines. For purposes of the instant action, the only countermeasures applicable to Plaintiffs are the COVID-19 vaccines.

⁴ 42 U.S.C. § 247d-6e(a) (emphasis added).

epitome of a kangaroo court or a star chamber—a proceeding that ignores recognized standards of law and justice, is grossly unfair, and comes to a predetermined conclusion.

10. As a critical reminder: taxpayer funds were used to develop, test, purchase, distribute, and promote the vaccines. The federal government also mandated the vaccine through every avenue it legally could (and sometimes went beyond that until corrected by the judicial branch) or incentivized mandates by state and local governments or private employers and schools.

11. The government consistently tested limits in a stated effort to protect Americans from COVID-19. Indeed, according to Justice Gorsuch, during the COVID-19 pandemic, Americans experienced “the greatest intrusions on civil liberties in the peacetime history of this country.” *Arizona v. Mayorkas*, 143 S.Ct. 1312, 1314 (2023) (Gorsuch, J., concurring). Executive officials issued emergency decrees, shuttering businesses, schools, and churches; surveilling cities to enforce compliance with social distancing requirements under threat of criminal penalties; and divided cities and neighborhoods into color-coded zones that could be changed when challenged in the courtroom. *Id.* at 1314-15 (citing 10 cases of intrusions on civil liberties). The government painted the vaccine as the only way out of this crushing regime of restrictions on individual and civil rights that it imposed.

12. Now, having taken away Plaintiffs’ ability to obtain recompense from the manufacturers and/or administrators of the products that severely injured them, the government refuses to compensate those who heeded the call and suffered the most severe vaccine injuries and, in doing so, denies them even the most basic of due process measures. The CICP as it functions now is fundamentally inconsistent with Congress’ intent. CICP claims are consistently lost, ignored, denied, or caught up in the years-long purgatory of government bureaucracy. The

compensation, if any, is neither timely nor adequate. Perhaps the decisions are uniform, but only in the sense that claims uniformly get lost in a black hole for years or are uniformly denied.

13. Congress could remedy the defects in CICIP by amending the PREP Act so that it satisfied Americans' constitutional rights and accomplishes the stated objective of providing timely, uniform, and adequate compensation to Plaintiffs and other individuals harmed by the COVID-19 vaccine. However, the legislation as currently drafted and implemented fails to provide the most basic protections required under the U.S. Constitution. The immunity to liability provisions within the PREP Act and the CICIP are inextricably intertwined. As such, the overarching rationale for providing liability protection to vaccine manufacturers under the PREP Act—that an **alternative and adequate remedy** for those injured by a COVID-19 vaccine exists—evaporates if the alternative and adequate remedy provided by Congress is itself unconstitutional. Accordingly, the PREP Act's immunity protections for vaccine manufacturers cannot stand as there is no constitutional alternative provided to vaccine injured citizens.

14. Plaintiffs respectfully request that the Court enter an order (i) declaring that those provisions of the PREP Act pertaining to CICIP, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, are unconstitutional and (ii) enjoining the federal government, pursuant to the Fifth Amendment to the U.S. Constitution, from enforcing those provisions of the PREP Act that provide liability protection, unless the government provides the vaccine injured a reasonable alternative remedy with the following basic legal and constitutional protections:

- A. identify the name, title, and educational credentials of the individuals who are deciding COVID-19 vaccine injury claims;
- B. confirm that such decision-makers have no conflicts of interest and provide a process to challenge any particular decision-maker for conflicts of interest;
- C. identify any expert witnesses or consultants used by the government in making determinations;
- D. provide claimants with a reasonable opportunity to question witnesses, including experts, or review evidence used against claimants;

- E. provide claimants with a reasonable opportunity to question or obtain discovery from such experts, including producing copies of any expert reports;
- F. allow claimants the opportunity to present expert witnesses on their behalf;
- G. provide claimants with a reasonable opportunity to obtain discovery, including discovery from companies that manufactured or distributed the COVID-19 vaccines that harmed them;
- H. produce copies of any records or documents used to decide COVID-19 vaccine injury claims;
- I. provide notice to claimants and a reasonable opportunity to be heard before any decision;
- J. allow claimants to seek reasonable recovery for all damages suffered, including related to medical treatment, loss of income or earning potential, death, and/or pain, suffering, and emotional distress;
- K. provide that attorneys are eligible for attorneys' fees and costs as long as the claim was submitted in good faith and with a reasonable basis;
- L. provide an appeal/judicial review of a COVID-19 vaccine injury decision in a court of law; and/or
- M. maintain a written record of any hearings or proceedings for judicial review.

JURISDICTION

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1343.

16. This action arises under the Fifth Amendment to the United States Constitution.

PARTIES

A. Plaintiffs

17. Plaintiff Carolina Bourque is and at all relevant times has been a citizen and domiciliary of the State of Louisiana, residing in Youngsville, LA.

18. Plaintiff Emma Burkey is and at all relevant times has been a citizen and domiciliary of the State of Nevada, residing in Henderson, NV.

19. Plaintiff Christopher Cody Flint is and at all relevant times has been a citizen and domiciliary of the State of Mississippi, currently residing in Boyle, MS.

20. Plaintiff Michelle Zimmerman is and at all relevant times has been a citizen and domiciliary of the State of Washington, residing in Seattle, WA.

21. Plaintiff Jessica Krogmeier is and at all relevant times has been a citizen and domiciliary of the State of Iowa, residing in Donnellson, IA.

B. Defendants

22. Defendant United States Department of Health and Human Services (“**HHS**”) is a cabinet-level executive branch department within the United States Federal Government.

23. Defendant United States Health Resources and Services Administration (“**HRSA**”) is an Operating Division of HHS. HRSA administers the Countermeasures Injury Compensation Program (“**CICP**”), at issue in this suit.

24. Defendant John Does 1-3 (collectively, “**John Does**”) are individuals charged with supervising, managing, directing, or operating CICP. As set forth below, various Plaintiffs have requested identification of John Does, but CICP, HHS, and/or HRSA have not disclosed their identities to date.

STATEMENT OF FACTS

A. Carolina Bourque

25. In 2021, Carolina had been working as a biologist at the Louisiana Department of Wildlife and Fisheries for 13 years. In her role as an oyster manager biologist, she traveled extensively, participated in conferences and meetings nationwide, and was responsible for managing and protecting Louisiana’s oyster natural resources, including management of approximately 1.7 million acres of public oyster areas. Although Carolina managed seasonal allergies, she was in good overall health. She enjoyed a full and active life.

26. Everything changed on March 17, 2021, when Carolina received a Moderna COVID-19 vaccine and immediately suffered an anaphylactic-type reaction, with a rash on her arm and torso, tachycardia, dizziness, shortness of breath, and intense gastrointestinal

pains that would last for months. She lost her hearing and had veins that popped on the inside of her arm within two hours after receiving the vaccine.

27. On March 23, 2021, when her ongoing medical issues had not improved, Carolina visited her primary care physician. Her physician took blood work, completed an ultrasound of Carolina's abdominal area, and referred her to a gastroenterologist. Within a few weeks, she also visited an ear, nose, and throat ("ENT") specialist and a pain management doctor. Doctors performed an MRI and multiple other tests.

28. On June 17, 2021, at the recommendation of her physicians, Carolina proceeded with a second COVID-19 shot. She was immediately dizzy and stayed at the pharmacy for 30 minutes so she would not faint. By the second day, Carolina could not get out of bed. Her leg and arms were weak, and she developed facial paralysis/Bell's palsy and migraines. Carolina became dizzy and confused. She could barely perform work at her computer because her eyesight became blurry, preventing her from reading the words on the screen.

29. Carolina's primary care physician initially identified an adverse vaccine reaction to the COVID-19 vaccine, but he was unwilling to make a report to the Vaccine Adverse Event Reporting System ("VAERS"). Carolina filed a VAERS report herself (ID #1502325) on July 26, 2021. She later filed an updated VAERS report (ID #1951207) on December 15, 2021. A true and accurate copy of the December 15, 2021 VAERS report is attached as **Exhibit 1**.

30. After multiple new doctor visits, including a neurologist, rheumatologist, and an ENT specialist, Carolina was ultimately diagnosed with dysautonomia/autonomic dysfunction, small fiber neuropathy, peripheral neuropathy, mast cell activation syndrome, hemiplegic migraines, vestibular migraines, and chronic fatigue syndrome, among other diagnoses. Even after approximately 36 months, Carolina continues to receive new diagnoses. Doctors have been baffled

by her vast array of symptoms. As of the date of this Complaint, Carolina continues to search for a knowledgeable neurologist who can develop a better treatment plan, and she continues to get referrals to other specialists to see who can help her.

31. Carolina is unable to complete basic tasks, including driving more than a 15-minute radius, speaking in public, or attending any event with loud noises or lights. She suffers from brain fog, fatigue, and dizziness on a daily basis. Carolina also deals with inflammation and painful sensations that vary between shocking pains to tingling and numbness throughout her body.

32. Carolina's injuries forced her to leave her position as an oyster manager to become a low-level biologist, with lower pay, more basic daily tasks, and minimal public contact, phone calls, and travel. Carolina now works from home three days a week at a computer station, and once a week she rides to work with her husband because she often cannot drive without getting confused and dizzy. Carolina takes daily breaks and, most weeks, she cannot fulfill her basic 40-hour work schedule.

33. Since her injury, Carolina has spent over \$30,000 on medical expenses, including ongoing testing and treatment. Despite visits to numerous specialists, special diets, and supplements, Carolina has yet to find effective treatments to manage her vaccine injuries. She sees no pathway to improvement going forward.

34. In March 2022, Carolina made a claim with the CICP before the expiration of her one-year deadline. Carolina directed her physicians to submit medical records, both in paper and online via the Injury Compensation electronic submission website, associating her new symptoms and diagnoses to a vaccine reaction. Almost a year later, CICP representatives continued to claim that they did not have any of her records. They could provide no guidance regarding the timeline for determining claims nor identify who would be reviewing and deciding claims. An excerpt of a

transcribed conversation Carolina had with CICP on February 8, 2023, more than a year after submitting her request for benefits, follows:

0:03:33 Carolina Bourque

So you have received the medical records, correct?

0:03:38 CICP Representative (Juan)

No, they have not. They either have not or they have not updated.

0:03:42 Carolina Bourque

Because I know for sure two doctors have submitted the medical records. So who decides to upload, you know, the medical records or what's the timeline on that? It was submitted last year.

0:03:57 CICP Representative (Juan)

So unfortunately, **we don't really have a time frame**. But what I can do is I can get your information down, have the department take a look into it, give you a call back and confirm with you which documents were received or if they need any additional documentation.

0:04:13 Carolina Bourque

...[W]ho decides, you know, on the documentation, like, who do you guys have like, a panel to review the documentation or or how does it work?

0:04:26 CICP Representative (Juan)

The documentation is reviewed by medical staff team members. They, they go ahead and review those records and, and make that decision.

0:04:34 Carolina Bourque

OK. And this medical team like, where are they? You know, are they hired by you guys, specifically, contractors? Are they like consultants or something?

0:04:52 CICP Representative (Juan)

I'm, I'm not sure. I think the credentials are in the medical field, so they're, they're most likely doctors. From what I'm being told, that's, that's who essentially reviews those records. It's not someone who isn't qualified, and that's what I can assure you, as, as that they've informed us that they are accredited and they are knowledgeable in that field. So when they are reviewing the medical records you can rest assured it's someone that's qualified to review them.

0:05:25 Carolina Bourque

OK, now what happens if there's more than 240 days passed and there's no determination, especially for example, in my case, I submitted March of last year and it's close to 365 days. So what, what happens?

0:05:44 CICP Representative (Juan)

So it's, **it's not uncommon that it's been this long. We've had individuals as well in your situation.** What we do is we just escalate the matter and have the department contact you directly and kind of, like, reassure you that they, they still have your paperwork. In many cases ma'am, I'm going to be quite honest with you the medical records that I've sent, they are provided. It's just more so on the department to update that information, There, **I believe there may be a big backlog** and not giving any, any information in regards to that, but it's it's, it's better if we just have them contact you.

A true and accurate copy of a recording of Carolina's first telephone call to CICP on February 8, 2023 is attached as **Exhibit 2.**

35. Carolina called CICP a second time and spoke with a second CICP representative, who again could provide no timeframe for claim determination:

0:02:15 CICP Representative (Jennifer)

[CICP] does not give updates online. You receive letters throughout the process. **It is a delayed process.** So it does take time to receive letters from the CICP.

0:02:25 Carolina Bourque

So it takes time. Like how long? What's the usual time for revision for each application? I submitted mine last year.

0:02:35 CICP Representative (Jennifer)

There's no time frame, how long it can take.

0:02:38 Carolina Bourque

Oh, there's no time frame.

0:00:2:40 CICP Representative (Jennifer)

No ma'am.

A true and accurate copy of a recording of Carolina's second telephone call to CICP on February 8, 2023 is attached as **Exhibit 3.**

36. More than a year and a half after submitting her claim, Carolina has received no determination or updates from CICP.

B. Emma Burkey

37. Emma Burkey was a healthy 18-year-old senior attending high school in Nevada. By the spring of 2021, Emma had a 4.3 GPA, attended classes online, had a black belt in karate,

and juggled multiple part-time jobs. Emma planned to attend UNLV in the fall. Although she was undecided in her major, Emma always knew that her career path would involve children.

38. On March 20, 2021, Emma received the J&J COVID-19 vaccine because she believed it would help keep the children around her safe. Emma trusted J&J because it is known as a “baby [products] company.”

39. For a week and a half following her vaccination, Emma experienced intermittent nausea, increased heart rate, and headaches. Emma was told to expect these side effects, so she was not immediately concerned.

40. On March 31, 2021, Emma returned to work with her mother. She left work early because of migraine headaches. On April 1, 2021, Emma went to work again. She experienced severe headaches, but she finished the day and went to bed early that evening.

41. Emma woke early in the morning on April 2, vomited in bed, and had her first seizure, 11 days after her vaccination.

42. Emma was immediately transported by ambulance to the emergency room at Saint Rose Dominican Hospital in Las Vegas. Scans revealed that Emma had a small brain bleed, which progressively worsened, as she developed Cerebral Venous Sinus Thrombosis due to blood clotting in her brain. Her brain hemorrhaged and she began seizing constantly, with rapid temperature and heart rate increases. By the end of the day on April 2, 2021, Emma was no longer responsive.

43. Emma’s infectious disease doctor, Dr. Brian Lipman, immediately suspected that Emma was suffering an adverse reaction to the J&J vaccine because Emma’s symptoms mirrored

adverse events associated with the AstraZeneca vaccine in Europe.⁵ Doctors at Saint Rose began calling and emailing the CDC and J&J requesting guidance. They received no response from either the health agency or the pharmaceutical company over the weekend.

44. By the early hours of April 3, 2021, Emma's parents made the difficult decision to allow doctors to place Emma in a medically induced coma and intubate her.

45. The next day, April 4, doctors informed Emma's parents that their daughter would likely die if they did not perform brain surgery to open the clots in her brain. They proceeded with surgery. Unfortunately, a post-surgery MRI showed more clots filling inside Emma's brain. Doctors met with Emma's parents again and determined they needed to perform a second brain surgery.

46. Emma endured a second brain surgery on April 5, 2021. She did not wake up. Brain scans showed no blood flow through the top of Emma's head after the surgery. The clots in Emma's brain had become so severe that physicians believed she would remain in a persistent vegetative state for the rest of her life.

47. Doctors at Saint Rose had exhausted all options. They continued to request guidance from the federal government and J&J. Again, no response was provided. Hospital leaders recommended that they search nationwide for another hospital that could help.

48. On April 6, 2021, Emma was transferred to the Neurologic Intensive Care Unit at Loma Linda University Hospital in California. Two days later, physicians at Loma Linda performed a third brain surgery on Emma.

⁵ <https://www.youtube.com/watch?v=iy9qBxGbGPw> at 1:25 (local news interview with Emma's doctor, Dr. Lipman, speaking about her case).

49. On April 9, 2021, Emma began to show signs that she was slowly regaining consciousness.

50. Emma's story gained national attention in April 2021, when the FDA paused the rollout of the J&J vaccine because Emma and five other women between the ages of 18 and 48 suffered the same catastrophic reaction.⁶ As of January 2022, the CDC reported that eight people (six women, two men) had died from similar conditions shortly after receiving the J&J COVID-19 shot.⁷

51. In the days and weeks that followed, Emma began taking small steps that previewed the long journey ahead. On April 15, Emma first awoke from her coma,⁸ but was left in a quadriplegic state and was constantly vomiting due to her inability to digest food. Emma eventually had her feeding tube removed on May 27, 2021.

52. After hundreds of hours of therapy in the hospital, Emma was discharged in August 2021. Her life now consists of neurologic restorative therapy five days per week, from 9 am until 3 pm. Medical professionals work with Emma every day to re-map areas of her brain that have been damaged. Emma continues to fight to regain motor function, including the ability to walk, write, and care for her own personal hygiene.

53. In addition to the obvious trauma Emma's family has been through in watching their daughter suffer and wonder if she would live and, if so, with what quality of life, Emma's

⁶ *Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine*, FDA, (Apr. 13, 2021), <https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>.

⁷ *Use of the Jannsen (Johnson & Johnson) COVID-19 Vaccine: Updated Interim Recommendations from the Advisory Committee on Immunization Practices* (Jan. 21, 2022), CDC, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a4.htm>.

⁸ See <https://www.youtube.com/shorts/M2iiUxnEW3M>.

family has faced increased insurance premiums because of the ongoing medical expenses. The first bill they received was for \$650,000 and they have continued since then.

54. Emma's family had to purchase a new home to accommodate her condition. They moved from the family home that was almost fully paid off and into a one-story home with an open floorplan that is easier for Emma to navigate. Emma's family now has a \$520,000 mortgage, having bought their home at the peak of the market, which they did not anticipate as they approached retirement age. Emma's family also purchased and repaired a wheelchair-accessible van, at an estimated cost of \$60,000. Because of the mounting repairs on the van, Emma's family purchased another used wheelchair van for over \$49,000. Emma's dad drives her to and from physical therapy, a 36-mile round trip, two times a day (72 miles per day), five days per week, spending hundreds of dollars on gas. They also rented a home while searching for a new home and spent thousands of dollars while at Loma Linda.

55. Emma submitted a claim to CICP over two years ago, in November 2021. When asked about the timeframe by Emma's mother, CICP representatives provided no timeline for deciding her claim, stating repeatedly and coldly that it would be a "hot minute" until any decision was made.

56. On January 5, 2024, Emma received a letter from HRSA dated December 20, 2023, notifying her that CICP had determined she was eligible for CICP benefits. Emma and her mother are now in the arduous process of collecting and submitting information for calculation of reimbursement for medical expenses and lost employment income.

C. Cody Flint

57. Cody Flint is a husband, father of two boys and an experienced pilot from Mississippi with over 10,000 flight hours. For 15 years, he was employed as an agricultural crop-

dusting pilot. As a requirement of his position, Cody was required by law to obtain annual Federal Aviation Administration (“FAA”) physicals to keep his pilot license current. He has done so every year since he was 17 years old. Cody’s annual physicals, including his last FAA flight physical in January 2021, showed he was in excellent health, with no pre-existing conditions.

58. On February 1, 2021, only twelve days after his most recent FAA flight physical, Cody received his first COVID-19 Pfizer vaccination due to extreme pressure to do so from his employer. Within 30 minutes, he developed a severe headache which moved down the back of his neck and became a burning sensation at the base of his skull. Cody became dizzy, and his eyes could not focus properly.

59. On February 3, 2021, Cody resumed flying after observing the 48 hour no-fly rule required of pilots after COVID-19 vaccination. Immediately after takeoff on this crop-dusting flight (for which he was the only pilot and occupant of the plane), Cody experienced tunnel vision. Approximately one hour into the flight, his condition rapidly deteriorated with intensified headache, cold sweats, worsening dizziness, visual changes, disorientation, and uncontrollable shaking. Cody lost consciousness multiple times during the flight, but against extreme odds he was able to land safely before losing consciousness again and having to be pulled from the plane — none of which he recalls. Cody was flying a non-pressurized plane at an altitude no higher than 200 feet.

60. Cody was diagnosed with vertigo and a subsequent MRI and CT scan of his brain revealed bilateral ethmoid, maxillary, sphenoid, and frontal sinus inflammatory changes, and bilateral paranasal sinus inflammatory changes. Cody’s symptoms progressed, and he was prescribed various medications that prevented him from operating an aircraft. On February 12, 2021, Cody submitted a VAERS report documenting his injuries. A true and accurate copy of

Cody's February 12, 2021 VAERS report is attached as **Exhibit 4**. Cody sought medical care from several physicians, one of whom stated, "I think that shot made you one sick son of a bitch," and each of whom noted his rapid onset of symptoms post-vaccination. In fact, Pfizer reached out to one of Cody's physicians regarding his VAERS Report.

61. After seeing numerous doctors, Cody was ultimately diagnosed with left and right perilymphatic fistulas (a tear in the membranes that separate the air-filled middle and fluid-filled inner ear), elevated intracranial pressure, and bilateral eustachian tube dysfunction. Cody's simultaneous left and right perilymphatic fistulas, highly increased intracranial pressure, and rapid onset of a severe headache were all indicators of a vaccine injury.

62. On March 25 and June 3, 2021, Cody underwent surgery for left and right perilymphatic fistula repairs, bilateral ventilation tube placement, microdissection, and a lumbar puncture. He continues to suffer from ongoing symptoms and can no longer work as a pilot.

63. On April 25, 2021, Cody submitted his Request for Benefits form to CICP. Over a year later, after dozens of follow-ups by Cody, and after United States Senator Cindy Hyde-Smith contacted the CICP multiple times and even questioned the HHS Secretary regarding Cody's case during a May 4, 2022 public hearing,⁹ Cody's request was denied on May 25, 2022. A true and accurate copy of the CICP denial letter signed by George Grimes, M.D. is attached as **Exhibit 5**.

64. The denial letter absurdly stated that "barotrauma from flying is a known cause of perilymphatic fistulas, and the symptoms of the perilymphatic fistulas (severe vertigo) began while flying." This completely ignores that Cody was flying (as he did for 15 years) in an unpressurized plane at an altitude no greater than 200 feet, which would not induce barotrauma. In fact,

⁹ U.S. Senator Cindy Hyde-Smith, *Senator Hyde-Smith Cites Mississippi Case in Questioning HHS Injury Compensation Program*, YouTube (May 4, 2022), <https://www.youtube.com/watch?v=YGAhSLqFV9A>.

barotrauma was the first condition ruled out by Cody's doctors because pilots do not suffer barotrauma by flying a few hundred feet above sea level in an unpressured cabin. By comparison, commercial airline pilots and passengers fly 8,000 feet above sea level (40 times higher) in a pressurized cabin and would face an exponentially greater risk of barotrauma.

65. On June 15, 2022, pursuant to CICP processes, Cody requested reconsideration of the denial of benefits. CICP denied Cody's request for reconsideration on January 18, 2023 — 21 months after Cody submitted his original request.

66. Cody's salary is now reduced to 20% of what he had been making as a pilot. Compounding that ongoing loss, Cody did not have health insurance at the time of his vaccination and resulting injuries. He has already spent his family's entire savings, including his children's future college tuition, in an effort to get well enough to return to flying. That was a futile attempt that financially buried his family. His doctors tell him he needs significantly more treatment, but he cannot afford to get it.

D. Michelle Zimmerman

67. Prior to her COVID-19 vaccination, Michelle Zimmerman was a book author, published in five languages, and a researcher commissioned by General Motors and the International Society for Technology in Education. She had a meeting scheduled with the education advisor to Washington Governor Jay Inslee the week of her COVID-19 vaccination and was in the top running for the Global Teacher Prize.

68. Michelle was a full-time K-12 worker and STEM educator in Renton, Washington. She was highly physically active when HHS issued a directive to make available and administer

vaccines to teachers, childcare workers, and staff.¹⁰ A true and accurate copy of the White House Press Release, dated March 7, 2021, concerning the prioritization of COVID-19 vaccines for educators is attached as **Exhibit 6**. Consistent with these directives, Michelle's local public health officials confirmed she was required to obtain at least one dose of the COVID-19 vaccine by the end of March 2021.

69. On March 14, 2021, in an effort to remain in compliance with the President's authorization for frontline education workers in K-12 schools to obtain a first dose of the COVID-19 vaccine by the end of March 2021, to allow her to remain in a teaching position, and to set a good example for her students and those who were hesitant to get vaccinated with a new product, Michelle went to a mass vaccination site in King County, Washington. Michelle received the J&J COVID-19 vaccine.

70. Moments after her shot, Michelle experienced shooting pain down her injection arm and wrist, and up to her left ear. Within 20 minutes of the injection, Michelle began experiencing tongue and throat swelling (anaphylaxis), which was recorded as an adverse event by healthcare officials at the mass vaccination site. Because those administering her vaccine failed to follow requirements for administering a vaccine under emergency use authorization ("EUA") and did not send her for medical observation or treatment, Michelle's medical condition worsened. Michelle has since experienced irreversible brain and vision damage.

¹⁰ See *Secretarial Directive for Prioritization of COVID-19 Vaccines and Administration for Certain Educational and Child Care Workers*, HHS (March 2, 2021), <https://www.hhs.gov/sites/default/files/secretarial-directive-prioritization-covid-19-vaccines.pdf>.

71. Michelle had no underlying medical conditions before receiving the COVID-19 vaccination. Since receiving the shot, Michelle has been medically disabled and not medically cleared to return to work, drive, or travel, or to engage in cardio exercise.

72. Michelle now lives with her parents because she is unable to live independently. She cannot even drive herself to medical appointments.

73. Michelle continues to suffer from a host of medical conditions, including brain damage, vision damage, vestibular damage, vascular damage, blood clotting, mitochondrial damage, damage to gut microbiome, skin and hair loss, and nerve damage. She has also experienced a substantial shift in body composition, including muscle waste and muscle coordination impairment (ataxia), not explained by dietary changes. In the three years following her vaccine injury, extensive clinical and specialized medical testing have revealed no causes for her injuries other than the COVID-19 vaccine.

74. The frustration Michelle feels on a daily basis matches the devastation and severe physical pain of the physical symptoms. She had been saving all of her money to buy a house. Now, she could never hope to live independently and has instead burned away her savings on medical care.

75. Michelle learned through her own research that she could pursue benefits through CICP. In September 2021, she contacted CICP to request a guide for the standard for proof of causation that would be required so that she could be sure to submit all required information. CICP representatives advised Michelle that no standard or guideline existed, but that quantitative data and peer-reviewed, published scientific research would meet the standard for proof of causation.

76. On October 1, 2021, after spending weeks compiling it, Michelle submitted a Request for Benefits form to CICP through the electronic portal. Her claim package included 300

pages of her relevant medical records and proof of causation. Michelle received online confirmation that her application and medical records were received in October 2021.

77. Michelle repeatedly requested updates from CICP officials and confirmation that her medical records had been received. Initially, she spoke with a CICP representative named David who could not confirm a timeframe for when her claim would be processed. On November 22, 2021, Michelle received a return call from a customer service representative who identified herself as Phyllis. A true and accurate copy of a recorded excerpt of Michelle's November 22, 2021 telephone conversation is attached as **Exhibit 7**. During the call, Michelle was informed that CICP had no record of her claim, that she must re-apply and wait 40 days to see if the claim was posted on the system, and then repeat the process of re-applying if CICP lost her claim again. When Michelle asked to speak with a supervisor or to be given a supervisor's contact information, Phyllis responded that she could not provide that information. *Id.*

78. Months later, after multiple communications, Michelle was connected with Captain Dale Mishler, Chief of Countermeasures and Review Panel Branch. During their April 24, 2022 telephone conversation, Captain Mishler assured Michelle that, contrary to prior statements by CICP representatives, CICP had received her medical records. Captain Mishler also confirmed that CICP provides no guideline to the public regarding the required standard of proof to be applied:

05:38 Michelle Zimmerman

So there's not actually a published document that's made public for people to access prior to submitting the claims?

05:46 CICP Representative (Capt. Mishler)

Regarding?

05:48 Michelle Zimmerman

What you're using for the standard of proof. For example, what journals you're using, what medical research you're using, so that people have access to know what you are using to compare their submitted claims, and what your reviewers are using to determine if it meets those claims.

06:03 CICP Representative (Capt. Mishler)

Um, we're, we're using up to date, we're using, uh, PubMed, we're using the National Institutes of Health's, uh, medical library. Um, and all of those, all of the evidence has to be based in a peer reviewed published journal.

06:20 Michelle Zimmerman

And that makes sense, I under-, and I do understand that part. But what I'm saying is what guideline is available to the public — so before they submit their claim, they know what you're looking for, which journals you're using, which researchers you find acceptable or not — especially since...

06:35 CICP Representative (Capt. Mishler)

The [inaudible] guideline for that? No.

06:37 Michelle Zimmerman

Okay, so there is no guideline? Okay.

06:37 CICP Representative (Capt. Mishler)

No, no.

A true and accurate copy of a recorded excerpt of Michelle's April 24, 2022 telephone conversation is attached as **Exhibit 8**.

79. For over two years, CICP officials have delayed, providing contradictory answers without any indication that resolution of Michelle's claim is forthcoming. In March and April 2022, CICP told her that no case number had been assigned. But almost a year later, Michelle received an express mailer dated January 11, 2023, containing a letter backdated to January 1, 2022 (a federal holiday and weekend), with a case number, signed by Dr. George Grimes. A true and accurate copy of the letter and mailer are attached as **Exhibit 9**.

80. Michelle also received a letter in an extremely urgent mailer stating that CICP was missing medical records, even though she had been assured previously that her records were received. Michelle submitted records both online through the CICP electronic portal and via certified mail, but CICP repeatedly provided conflicting information.

81. Over two years after submitting her claim, there is no indication when a determination will be made on Michelle's claim. Michelle still suffers daily with all of the above-described symptoms and her life has not returned anywhere close to her pre-vaccination "normal."

E. Jessica Krogmeier

82. From 2004 through 2020, Jessica Krogmeier had extensive experience in the healthcare industry. During that time period, she attended nursing school and was employed in various roles as a respiratory therapist and registered nurse. She was ambitious, goal-oriented, and had dreams of advancing her education and moving into a nursing leadership position.

83. Jessica had resigned from her position in October 2020 to recover from a pregnancy loss.

84. While preparing to return to work in the summer of 2021, Jessica understood that the COVID-19 vaccine would be required for any nursing position she would obtain. Thus, on September 3, 2021, Jessica received her first Pfizer COVID-19 vaccine.

85. Before receiving her shot at a pharmacy, Jessica spent time discussing potential side effects with the pharmacist. Jessica was concerned because her son was getting surgery the following week. The pharmacist counted the number of days (four) on his fingers and told Jessica, "You should be fine by then." Jessica also expressed concerns because she was breastfeeding at the time. The pharmacist said he had just read a study out of Israel and he was comfortable with Jessica taking the shot, and that she could continue breastfeeding her daughter.

86. Immediately after receiving her first COVID-19 vaccine, Jessica felt dizziness, numbness, tingling, exhaustion, severe arm pain, chest pain, and the inability to sweat. A VAERS report (ID #1678480-1) was submitted on September 7, 2021. A true and accurate copy of Jessica's September 7, 2021 VAERS Report is attached as **Exhibit 10**.

87. Jessica was unable to stay with her infant daughter by herself for almost four weeks due to a host of ongoing and progressing symptoms following her COVID-19 vaccination.

88. Before receiving the COVID-19 vaccine, Jessica rarely had to go to the doctor. Since receiving the shot, Jessica has been evaluated by many specialists and had multiple diagnostic tests and laboratory tests. Jessica's providers consistently noted the rapid onset of symptoms after she received the COVID-19 vaccine.

89. Following her vaccine, Jessica has been diagnosed with small fiber neuropathy, pre-diabetes, and autonomic dysfunction. She continues to suffer, at various times, from dizziness, extreme fatigue, internal tremors, tinnitus, painful periods, numbness and tingling in all the limbs, ear pain and fullness with changes in hearing, chest pain, elevated heart rate, trigeminal nerve pain, brain fog, abdominal pain, diarrhea, lumps under the skin, and orthostatic lightheadedness.

90. Jessica's vaccine injuries have also significantly limited her employment prospects. She currently works on a reduced schedule as a cardiac and pulmonary rehab nurse because she cannot predict how she will feel from day to day. Although she performs her duties to the best of her ability, Jessica can barely work three days per week and could not consider a more rigorous nursing position. Today, Jessica just hopes to feel well enough to get out of bed, to endure the dizziness, joint pains, and burning sensations, and to work part-time for as many years as she has left.

91. To date, Jessica has spent close to \$10,000 out of pocket to cover her ongoing medical treatments and out-of-state travel to see specialists, with this amount expected to increase. Because her vaccine injury has significantly limited her ability to manage a full-time workload, Jessica has also lost at least \$35,000 per year in earning potential. Jessica was also forced to withdraw \$10,000 from her 401(k) account to make ends meet.

92. Jessica continued breastfeeding her daughter after she received the COVID-19 vaccine, even despite her vaccine injury, as she had been told by the pharmacist administering the vaccine that she could continue to breastfeed. Jessica's daughter had been a healthy, growing baby for the first four months of her life. After Jessica received the COVID-19 vaccine and continued to breastfeed, her infant daughter suffered from rashes, diarrhea, and stopped gaining weight for six months. Jessica's daughter was hospitalized and received breathing treatments and was diagnosed with asthma. Her daughter has since received steroid treatments six times.

93. In September 2021, Jessica submitted an online request for benefits to CICP. Jessica also submitted a CICP claim with supporting documentation for her daughter before the one-year deadline in September 2022. To date, she has not received a response to either request.

94. On February 9, 2023, Jessica called CICP to confirm the status of her claim. Although Jessica's physicians had already submitted records, the CICP representative informed Jessica that no records had been provided and that CICP had no timeline for determining claims. The following is an excerpt from a transcript of that call:

0:07:47 Jessica Krogmeier

OK. Well, what is the timeline for deciding the request, then, once you get everything that you need?

0:07:54 CICP Representative (Phyllis)

There is no timeline.

0:07:56 Jessica Krogmeier

OK.

0:07:56 CICP Representative (Phyllis)

The only timeline on this is the one for opening a claim. You have one year to open the claim, but **after that there's no timeline.**

0:08:04 Jessica Krogmeier

So it could take several years to decide a claim.

0:08:08 CICP Representative (Phyllis)

It can. It can, but right now with yours, it's not going anywhere because we don't have medical records. So it's still just sitting in the beginning stage.

0:08:18 Jessica Krogmeier

And that's interesting because I sent them, so I'll have to check into that. But excuse me, what happens if more than 240 days passed? Then? Because I've seen some stuff about that and there hasn't been a determination what happens then?

0:08:33 CICIP Representative (Phyllis)

You know **they have however long they need to make a determination.**

A true and accurate copy of Jessica's recorded telephone call to CICIP on February 9, 2023 is attached as **Exhibit 11.**

95. During this call and a subsequent call, the CICIP representative confirmed that (i) Jessica's claim would be decided by an unidentified team of doctors, lawyers, or other individuals; (ii) requests for reconsideration may or may not be determined by the same team or teams; and (iii) the representative did not know whether individuals deciding claims have any conflicts of interest. A true and accurate copy of Jessica's second recorded telephone call to CICIP on February 9, 2023 is attached as **Exhibit 12.**

F. The PREP Act and CICIP

96. CICIP was established as part of the Public Readiness and Emergency Preparedness Act of 2005 ("**PREP Act**")¹¹ to provide "timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a).

97. The PREP Act authorizes the HHS Secretary to issue a declaration that "a disease or other health condition or other threat to health constitutes a public health emergency." 42 U.S.C.

¹¹ Public Readiness and Emergency Preparedness Act of 2005, Pub L. No. 109-148, 42 U.S.C. §§ 247d-6d, 247d-6e (2005).

§ 247d-6d(b).

98. The PREP Act provides immunity to “covered persons” from liability under federal and state law for “all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.” 42 U.S.C. § 247d-6d(a)(1).

99. The PREP Act carves out a narrow exception to immunity for cases of serious injury or death caused through “willful misconduct.” In cases of willful misconduct, the injured person or the person’s survivors must first file in CICP and, if denied or if they do not accept the offered compensation, must then file suit in the United States District Court for the District of Columbia and prove the injuries by clear and convincing evidence. 42 U.S.C. § 247d-6d(c)(3), (e)(1).¹² In all cases aside from willful misconduct claims, individuals injured by a covered countermeasure must also seek redress from CICP without any option of filing suit in court.

G. Claims for COVID-19 Vaccine Injuries Under CICP

100. On January 31, 2020, the former HHS Secretary, Alex M. Azar II, declared a public health emergency for the entire United States in response to the COVID-19 outbreak. The January 2020 declaration and thirteen subsequent renewals provided protections to, among others, manufacturers and distributors of COVID-19 vaccines (countermeasures).

101. As of January 1, 2024, 12,854 CICP claims have been filed related to COVID-19 countermeasures. The statistics speak for themselves: to date, CICP has compensated only **11** of

¹² For most claims against manufacturers or distributors with respect to a covered countermeasure, either the Secretary of HHS or the Attorney General must first initiate an enforcement action as a condition of suit. *See* 42 U.S.C. § 247d-6d(c)(5)(A).

those claims, 10 for myocarditis/myopericarditis and one for anaphylaxis.¹³ The average payout on COVID-19 vaccine injury claims to date is \$3,743.18. By comparison, CICIP's average payout on injuries related to the H1N1 vaccine was \$198,450.12.¹⁴ Over 82% (10,640/12,854) of the COVID-19 countermeasure claims remain "pending review or in review." In rare instances where a decision has been reached, 98% of those COVID-19 countermeasure claims have been denied (2,174/2,214). CICIP has awarded compensation to a lamentable 0.08% of total COVID-19 claimants (11/12,854), and benefits determinations remain pending for 0.22% of total COVID-19 claimants (28/12,854).¹⁵

102. The staff at CICIP, which account for over 94% of the budget with their salaries and administrative costs,¹⁶ spend their days looking for every possible technicality to throw out otherwise legitimate claims. Of the 2,214 claims for which CICIP has issued a decision, it has denied 2,174. Of those denied, 1,320 were denied because these seriously injured Americans did not file within one year of receiving the vaccine,¹⁷ a time period set by the PREP Act. *See* 42 U.S.C. § 239a (d). Another 340 were denied because medical records were not submitted.¹⁸ And 251 were denied because the product was not specified or was not covered by the CICIP.¹⁹ Only 263 have been dismissed for not meeting the standard of proof and/or a covered injury was not

¹³ *Countermeasure Injury Compensation Program (CICIP) Data*, HRSA, (Dec. 1, 2023), <https://www.hrsa.gov/cicp/cicp-data>.

¹⁴ *Table 4. CICIP Claims Compensated (Fiscal Years 2010-2023)*, HRSA, <https://www.hrsa.gov/cicp/cicp-data/table-4>.

¹⁵ *Countermeasure Injury Compensation Program (CICIP) Data*, HRSA, (Dec. 1, 2023), <https://www.hrsa.gov/cicp/cicp-data>.

¹⁶ *See* Compl. ¶¶ 118-19.

¹⁷ *See* <https://www.hrsa.gov/cicp/cicp-data>.

¹⁸ *Id.*

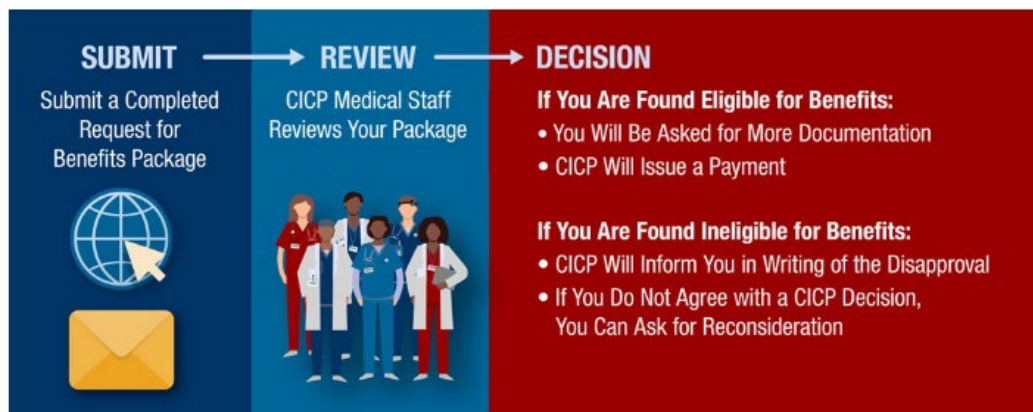
¹⁹ *Id.*

sustained—these are the only substantive decisions to date.²⁰

103. The rate at which CICP has been deciding claims since 2023 is around 90 claims per month²¹ but that will, as it runs out of technical reasons, likely slow down greatly as CICP will need to find other reasons to continue denying claims or giving near-nothing compensation. This is because CICP has almost no money to pay out compensable injuries even if it were not a star chamber. The added insult that many who are seriously injured will have of waiting years, possibly a decade and far more for others, goes beyond a deprivation—it is the precise form of government tyranny this country was founded to stand against.

104. CICP's process is shrouded in secrecy. Although only Defendants have full access to their internal policies and procedures for deciding and rejecting requests for compensation, Plaintiffs identify all of the facts presently known below about the claims submission and review process.

105. HRSA's website²² describes the process as follows:



²⁰ *Id.*

²¹ See Transcript of *House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic Holds Hearing on Assessing Vaccine Safety Systems*, February 15, 2024, at **Exhibit 13**. Even at this rate, it will take approximately 10 years to adjudicate the current requests for benefits submitted to the program assuming no further requests are submitted.

²² See <https://www.hrsa.gov/cicp> (last accessed March 7, 2024).

106. Thus, publicly available information suggests that the process for submitting a COVID-19 vaccine injury claim, or a “Request for Benefits” to CICP has four steps:

- First, a claimant submits a Request for Benefits Package to CICP, via mail or the electronic portal available on the CICP website. The Request for Benefits Package is comprised of (i) a completed CICP Request for Benefits Form;²³ (ii) a completed Authorization for Use or Disclosure of Health Information Form for each health care provider that treated the claimant;²⁴ (iii) proof of administration or use of a COVID-19 vaccine; and (iv) medical records and hospital records on or after the date of administration of the COVID-19 vaccine, and medical records for one year prior to use or administration of the COVID-19 vaccine, as necessary, to show pre-existing medical history.
- Second, after submitting the Request for Benefits Package, the claimant’s case is placed in the CICP queue for review by unidentified “CICP medical staff.” CICP’s website states that “the time it takes for the CICP to process a Request for Benefits depends partly on the complexity of [the] case.”²⁵
- Third, CICP makes an eligibility determination. If eligible, CICP may request additional documentation to determine how much compensation should be provided. If not approved, CICP will provide written notice that the claim has been denied.
- Fourth, when CICP issues a denial, the claimant may request reconsideration from HHS within 60 days by mail (to the same address to which the original Request for Benefits was submitted).²⁶

107. Beyond this high-level information provided online by the government, there are very few details concerning the CICP process available to the public.

²³ See <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-request-form.pdf> (last accessed March 7, 2024).

²⁴ See <https://www.hrsa.gov/sites/default/files/hrsa/cicp/cicp-authorization-form.pdf> (last accessed March 7, 2024).

²⁵ <https://www.hrsa.gov/cicp/faq> (see question “How much time does it take to process my Request for Benefits?”).

²⁶ <https://www.hrsa.gov/cicp/faq> (see question “What if the CICP determines that I am not eligible for benefits?”).

H. Lack of Transparency and Safeguards in CICP Process

108. As detailed above, Plaintiffs have attempted to obtain additional information from Defendants regarding Plaintiffs' respective Requests for Benefits. The paragraphs that follow describe Plaintiffs' findings to date.

109. Initially, claims are submitted (by electronic portal or by hard copy via mail) to unidentified CICP representatives for review.²⁷ The government refuses to identify the name, title, or educational credentials of the individuals deciding CICP claims. Defendants provide no opportunity to interact with, much less question or challenge, those who are deciding Plaintiffs' requests. In fact, in response to a FOIA request submitted to HRSA by undersigned counsel seeking "[a]ll records sufficient to identify all agency personnel involved with [CICP]," HRSA's response redacted all but two names of CICP personnel, stating, "Due to credible threats and harassment against the DICP [Division of Injury Compensation Programs] staff and to protect the safety and wellbeing of the DICP staff, we withheld the identities and contact information of DICP staff members below the Deputy Director-level." (**Exhibit 14.**)

110. Plaintiffs have no way to confirm whether any individuals deciding claims have any conflicts of interests, including whether any of them have ever reviewed, promoted, profited from, or mandated the COVID-19 vaccine.

²⁷ See <https://www.hrsa.gov/cicp/filing-process> ("Submission Instructions" state: Send your request for benefits by U.S. Postal Service mail or private courier service (e.g., FedEx or UPS) to the address below:

U.S. Department of Health and Human Services
Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, Room 8W-25A
Rockville, MD 20857.

111. The government provides no timeline for deciding requests. Plaintiffs have no way of tracking requests until they receive a case number at some uncertain time in the future.

112. The government provides no opportunity for discovery nor any method to request or review documents relied upon to reach its determination.

113. Defendants review claims according to unknown, undefined standards. The government provides no rubric, manual, or set of guidelines or standards that are used to decide requests. Instead, the government states that, “To establish a covered injury, the CICP must determine that the injury sustained was the direct result of the administration or use of a covered countermeasure. Under the Public Readiness and Emergency Preparedness Act (PREP Act), the CICP may only make such determinations based on compelling, reliable, valid, medical, and scientific evidence.”²⁸ This standard appears to be determined by unidentified individuals, based on unidentified information and evidence.

114. The government does not identify any expert witnesses or consultants used in making determinations. If the government relies on such experts or consultants, the government does not produce their written reports or materials or allow Plaintiffs the opportunity to question or cross-examine the experts. If the government does not rely upon experts, that presents other obvious concerns regarding the CICP process.

115. Plaintiffs cannot present their own expert or fact witnesses.

116. If denied benefits, Plaintiffs may request reconsideration from HHS within 60 days by mail (to the same address to which the original Request for Benefits was submitted).²⁹ The

²⁸ <https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred>.

²⁹ <https://www.hrsa.gov/cicp/faq> (see question “What if the CICP determines that I am not eligible for benefits?”).

same issues detailed above pertain to this “appeals” process and the same questions remain unanswered: who is deciding the request for reconsideration, what is the timeline, what is the standard of review?

117. Almost nothing else is disclosed about the inner workings of CICP.

I. Lack of CICP Funding

118. In addition to the complete lack of transparency about the program, CICP is also grossly underfunded. According to HRSA’s operating plan, HRSA budgeted \$5 million and \$7 million for “administration” of CICP in 2022 and 2023, respectively,³⁰ although hundreds of millions of doses of COVID-19 vaccines were administered.

119. CICP lacks cost-effectiveness and efficiency, with 94% of its total costs spent on administration rather than compensation to Plaintiffs and others. *See J. Zhao, et al, Reforming the Countermeasures Injury Compensation Program for COVID-19 and Beyond: An Economic Perspective*, DUKE J. OF LAW & THE BIOSCIENCES, p. 2 (2022).

120. CICP appears unable to adequately compensate — further evidence that the program is simply theatre. If COVID-19 claims were compensated at CICP’s historical rate, CICP would face around \$21.16 million in compensation outlays and \$317.94 million in total outlays which is 72.1 times its current balance. *Id.*

³⁰ *FY 2023 Operating Plan*, HRSA, <https://www.hrsa.gov/about/budget/operating-plan>.

J. Lack of Judicial Review

121. As described above, individuals harmed by a covered countermeasure like the COVID-19 vaccine cannot obtain judicial review of CICP determinations. *See* 42 U.S.C. § 247d-6e(d) (discussing exhaustion requirement and limited appeal rights).

122. Thus, CICP fundamentally differs from other compensation schemes such as the National Childhood Vaccine Injury Act of 1986 (“**Vaccine Act**”), which is subject to judicial oversight pursuant to specialized rules before the United States Court of Federal Claims (“**Vaccine Court**”).³¹

K. Lack of COVID-19 Vaccine Injury Table

123. Although the HHS Secretary is authorized to create a CICP COVID-19 injury table, he has not done so despite the passage of nearly three years after the widespread administration of the COVID-19 vaccine and the submission of 12,700 CICP claims and 1,683,039 reports made to VAERS to date following any COVID-19 vaccine.³²

124. According to the government, “An injury meeting the requirements of a covered countermeasures injury table [] **is presumed** to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause.”³³

³¹ Even the Vaccine Act’s (which does permit judicial review) flaws have been well documented. *See* “The Vaccine Injury Compensation Program: Addressing Needs and Improving Practices” (6th Rep. 2000), <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>.

³² <https://wonder.cdc.gov/vaers.html> (reflecting 1,683,039 events reported from COVID-19 vaccines as of November 24, 2023); *see also* <https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=VAX&EVENTS=ON&VAX%5b%5d=COVID19&VAX%5b%5d=COVID19-2&VAXTYPES=COVID-19> (utilizing government’s raw data but allowing users to save and send hyperlinks to searches and reflecting 1,683,039 events reported from COVID-19 vaccines).

³³ <https://www.hrsa.gov/cicp/criteria-demonstrate-covered-injury-occurred> (emphasis added).

Therefore, satisfying the necessary element of proving one has a covered injury is a lower standard for table injuries.

125. Because the Secretary has failed to create a COVID-19 vaccine injury table, Plaintiffs and all those requesting benefits from CICP need to meet the higher burden of proving the injury is a direct result of the administration of a COVID-19 vaccine.

L. Summary of Plaintiffs' Experiences with CICP Bring the Program's Issues into Sharp Focus

126. In March 2022, Carolina made a claim with the CICP. Almost a year later, CICP representatives continued to claim that they did not have any of her records. More than a year and a half after submitting her claim, Carolina has received no determination or updates from CICP.

127. Emma submitted a claim to CICP over two years ago, in November 2021. In the most recent call, CICP representatives provided no timeline for deciding her claim, stating repeatedly and coldly that it would be a "hot minute" until any decision was made.

128. On April 25, 2021, Cody submitted his Request for Benefits form to CICP. Over a year later, after dozens of follow-ups by Cody, and after United States Senator Cindy Hyde-Smith contacted the CICP multiple times,³⁴ Cody's request was denied on May 25, 2022. On June 15, 2022, pursuant to CICP processes, Cody requested reconsideration of the denial of benefits. CICP denied Cody's request for reconsideration on January 18, 2023.

129. On October 1, 2021, after spending weeks compiling it, Michelle submitted a Request for Benefits form to CICP through the electronic portal. Michelle received online confirmation that her application and medical records were received in October 2021. Michelle

³⁴ U.S. Senator Cindy Hyde-Smith, *Senator Hyde-Smith Cites Mississippi Case in Questioning HHS Injury Compensation Program*, YouTube (May 4, 2022), <https://www.youtube.com/watch?v=YGAhSLqFV9A>.

repeatedly requested updates from CICP officials and confirmation that her medical records had been received. For over two years, CICP officials have delayed, providing contradictory answers without any indication that resolution of Michelle's claim is forthcoming. Over two years later, there is no indication when a determination will be made on Michelle's claim.

130. In September 2021, Jessica submitted an online request for benefits to CICP. Jessica also submitted a CICP claim with supporting documentation for her daughter before the one-year deadline in September 2022. To date, she has not received a response to either request.

131. CICP operates entirely off the record and tramples on Plaintiffs' constitutional rights. The Court should strike down the PREP Act to the extent it fails to provide basic due process protections, transparency, and judicial oversight.

132. In sum, the PREP Act, extinguishes an individual's state and common law claims against "covered persons," and instead thrusts them into CICP, a program which offends the most basic safeguards of due process, including because **CICP does not and will not provide claimants:**

- a. the name, title, and educational credentials of the individual(s) deciding claims;
- b. confirmation that the individual(s) deciding claims have no conflicts of interest *or* provide a process to challenge potential conflicts of interest;
- c. the identity of the government's expert witnesses or consultants;
- d. an opportunity to obtain discovery;
- e. an opportunity to review and challenge evidence used against them;
- f. an opportunity to question and challenge witnesses relied upon to deny claims;
- g. an opportunity to obtain copies of any expert reports;
- h. an opportunity to obtain discovery from experts relied upon to deny claims;

- i. an opportunity to question and challenge experts relied upon to deny claims;
- j. an opportunity to present expert witnesses on their behalf;
- k. an opportunity to challenge the government's arguments and positions;
- l. notice and an opportunity to be heard orally before any decision;
- m. the ability to obtain compensation for their damages because an individual (i) must suffer a "serious injury," and even then, can only recover annual lost wages of up to \$50,000 and payor-of-last-resort-medical-expenses, and (ii) CICP cannot even pay these patently insufficient damages to even a tiny fraction of claimants due to underfunding;
- n. the ability to obtain attorney representation in most instances because, given the above, most attorneys will not handle these claims on contingency and it is not economical to pay an hourly rate for representation;
- o. a written record of any hearings or proceedings;
- p. a date by which a claim will be decided or any alternative for obtaining compensation irrespective of the duration CICP takes to decide a claim;
- q. the ability to seek any judicial review of any decision in a court of law;
- r. the right to present claims for damages in court; or
- s. the right to present claims before a civil jury.

133. These deficiencies hereinafter referred to as "**CICP Deprivations.**"

COUNT I

DECLARATORY JUDGMENT

134. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

135. Plaintiffs are entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that the PREP Act provisions which create the scheme providing liability protection and a

compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, violate the Fifth Amendment for deprivation of federal constitutional rights.

136. An actual and substantial controversy exists between Plaintiffs and Defendants as to their legal rights and duties with respect to whether the PREP Act provisions which create the scheme providing liability protection and a compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, violate the United States Constitution.

137. The case is presently justiciable because CICP's constitutional deficiencies apply to Plaintiffs, who are currently harmed by the CICP.

138. Absent the PREP Act, Plaintiffs could bring tort claims against vaccine manufacturers, distributors, administrators, and others who may be liable for their injuries under state law. However, Plaintiffs are foreclosed from bringing such claims because the PREP Act, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, provides liability protection and purports to establish a separate compensation process for COVID-19 vaccines. The PREP Act is unconstitutional. Plaintiffs are injured by this unconstitutional statute because they are barred from bringing claims that would otherwise exist under state law and no adequate remedy has been offered in the alternative.

139. Declaratory relief is therefore appropriate to resolve this controversy.

COUNT II

DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT – PROCEDURAL DUE PROCESS VIOLATION

140. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

141. The Fifth Amendment provides that no person shall “be deprived of life, liberty, or property, without due process of law.” U.S. Const. amend. V. Plaintiffs bring a claim under the Due Process Clause of the Fifth Amendment.

A. Plaintiffs’ Liberty or Property Interests at Stake

142. CICP implicates recognized liberty and property interests. The government extinguished Plaintiffs’ common law and state tort claims and replaced them with a federalized claim requiring proof of causation—a claim that has no discernible value.

143. First, the Supreme Court has long recognized that a cause of action is a species of property protected by the Due Process Clause. *See Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *see also Tulsa Prof’l Collection Serv. v. Pope*, 485 U.S. 478, 485 (1988) (holding that “little doubt remains” that a cause of action is a Constitutionally protected property interest); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 656 (S.D. Tex. 2004) (recognizing that a claim brought under the Vaccine Act “is a property interest protected by the Due Process Clause” (citing *Mullane v. Central Hanover Bank & Trust*, 339 U.S. 306 (1950)); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985); *Duke Power Co. v. Carolina Env’tl. Study Grp.*, 438 U.S. 59, 94 (1978) (stating that the Price-Anderson Act’s elimination of common law-based tort claims was a recognized property right and that the “Act impinges on that right by limiting recovery in major accidents” (Stewart, J., concurring)).

144. Second, to the extent the PREP Act provides a right to relief for Plaintiffs and others injured by COVID-19 vaccines, Plaintiffs have a liberty or property interest in seeking proper relief for their injuries. *See, e.g., Axon Enter. v. FTC*, 143 S.Ct. 890, 909 n.5 (2023) (Thomas, J., concurring) (discussing Supreme Court precedent equating government entitlements with core private rights); *see also Arthritis & Osteoporosis Clinic of E. Tex., P.A. v. Azar*, 450 F.Supp.3d 740, 747 (E.D. Tex. 2020) (granting preliminary injunction on plaintiff's due process claim where government failed to provide timely review of alleged overpayment of Medicare payments).

B. The Supreme Court's Procedural Due Process Test

145. The United States Supreme Court has considered three factors to determine whether government action satisfies procedural due process requirements:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Gibson v. Tex. Dep't of Ins., 700 F.3d 227, 239 (5th Cir. 2012) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976)).

146. Each of the three *Mathews v. Eldridge* factors considered by the Supreme Court favors striking down the PREP Act to the extent it violates fundamental procedural due process protections.

C. Plaintiffs' Private Interests

147. First, Plaintiffs' private interests in this case are beyond substantial. Each Plaintiff suffered injuries that substantially impact his or her body and, in turn, substantially impact his or her daily life, with typically devastating consequences. They have incurred, and continue to incur,

substantial medical bills and other expenses with no end in sight. Most of the Plaintiffs have had their careers destroyed. Plaintiffs require intensive medical care to get their health back to a point where they can work or pursue education again, if ever. Plaintiffs' and/or their families' livelihoods have been and will continue to be severely impacted.

148. Plaintiffs' private interests at issue extend even beyond their interest in their bodies and in their futures; their private interests also include having access to an appropriate process for obtaining compensation for the injuries they have suffered due to products developed, funded, authorized, licensed, promoted, and mandated by the government. Absent the PREP Act, Plaintiffs would be able to bring a private right of action against the manufacturers of the products that harmed them—a right that has existed for even longer than our nation has, the right to obtain relief for personal, physical, and emotional harms against tortfeasors. Specifically, Plaintiffs desire to prosecute claims for, *inter alia*, negligence, intentional infliction of emotional distress (“**IIED**”), and product liability against the pharmaceutical companies that designed and produced the products that injured them before a civil jury. However, Plaintiffs are foreclosed by the PREP Act from bringing such claims. The PREP Act extinguishes that right. At the same time, the government repeatedly assured every American including Plaintiffs that the product they were injecting was safe. Plaintiffs relied upon these government assurances when they decided to inject a product into their bodies. They were then severely harmed and CICA affords them no actual relief or remedy as detailed.

149. If, on the other hand, Plaintiffs had not been deprived of their claims, they could, *inter alia*, assert them in court; have a known trier of fact; confront the evidence, witnesses, and experts put on to defend against their claim; address any arguments opposing their claim; have an oral hearing regarding their claim; seek the full measure of their damages; and have a jury of their

peers. If they did not prevail, they would have access to a record of the hearing and proceedings and could appeal that determination. These and all the other traditional due process rights and protections eliminated by the PREP Act have been extinguished by the government, indefinitely, and all Plaintiffs are left with is an inability to bring traditional tort claims and the illusory hope of desperately needed compensation.³⁵ One would be hard-pressed to find a private right that was more adversely affected by government action.

D. CICIP's Established Record of Erroneous Deprivation and Value of Additional Safeguards

150. Second, the CICIP Deprivations provide a clear risk of erroneous deprivation because they allow CICIP to operate as a modern-day “star chamber” in which unidentified individuals review claims, under the alleged review of an unidentified panel. *See, e.g., Schultz v. Medina Valley Indep. Sch. Dist.*, 2011 U.S. Distr. 140330, W.D. Tex. (Dec. 6, 2011) (noting that early Americans came to the United States to escape England’s “star chamber of secret trials”) (citing JOHN SOUTHERDEN BURN, *THE STAR CHAMBER* (2008)).

151. The PREP Act’s non-existent procedural safeguards, including the CICIP Deprivations, will always generate “erroneous deprivations” of recognized property interests. *Mathews*, 424 U.S. at 335. While suffering from life-altering injuries, the PREP Act extinguished all of Plaintiffs’ state and common law claims and left them with the sole remedy of the filing a claim in the CICIP where Plaintiffs’ requests for information about, and from, CICIP and their attempts to receive compensation have been consistently ignored, delayed, or denied, without any

³⁵ In addition, the deprivation suffered by Plaintiffs is permanent. The PREP Act does not allow, at any time, civil causes of action to move forward against manufacturers or other covered persons. This factor also makes plain that Plaintiffs’ private interests have been severely and permanently adversely impacted by the government. *See Mathews*, 424 U.S. at 341 (holding that the “possible length of wrongful deprivation . . . is an important factor in assessing the impact of official action on the private interests.”).

meaningful opportunity to be heard or to challenge those making decisions on their claims.

152. The “erroneous deprivations” of rights is baked into the fabric of the PREP Act’s sole remedy it left Plaintiffs with, CICIP, both on its face and through its implementation by the Executive Branch. Plaintiffs incorporate herein the detailed allegations which explain how the PREP Act has extinguished an individual’s right to bring state and common law claims for their COVID-19 vaccine injuries and, in exchange, created the CICIP process which erroneously deprives claimants of virtually every due process right imaginable, including all of the CICIP Deprivations detailed *supra* ¶¶ 132-33. These CICIP Deprivations deprive Plaintiffs of: the right to know the identity/credentials of the individuals actually deciding their claims; the identity of any of the government’s expert witnesses relied upon to challenge their claims; any opportunity to obtain any discovery; any opportunity to challenge evidence used against them; any opportunity to challenge witnesses relied upon by the government to deny their claims; any opportunity to obtain copies of any expert reports relied upon by the government; any opportunity to challenge experts relied upon to deny their claims; any opportunity to present expert witnesses; any opportunity to challenge the government’s arguments; notice and any opportunity to have a hearing; the ability to obtain compensation for their damages because an individual must suffer a “serious injury,” and even then, can only recover annual lost wages of up to \$50,000 and payor-of-last-resort-medical-expenses, and CICIP cannot even pay these patently insufficient damages to even a tiny fraction of claimants due to underfunding; the ability to obtain legal representation in most instances due to the unconscionable cap on damages; a written record of any proceedings; a date by which a claim will be decided or any alternative for obtaining compensation irrespective of the duration CICIP takes to decide a claim; the ability to seek any judicial review in a court of law; and the right to present claims before a civil jury.

153. Of note, unlike other due process cases, here, there was an existing system of due process in place that was eliminated and there were substantive due process rights—state and common law claims—that were eliminated. Both deprivations happened at the same time upon the person suffering an injury. In contrast, in almost all other due process claims either there was no right to begin with—and only a government benefit conferred upon people—or there was never a constitutionally sufficient process with regard to adjudicating an existing right. The fact that the state and common law rights to bring a claim already had an adequate due process system that was extinguished makes this situation unlike almost all other due process cases and heightens the need for due process protections.

154. When analyzing what procedures are needed to avoid erroneously depriving Plaintiffs, the starting point is the already-existing due process procedures that existed prior to the government action and which were carefully honed over hundreds of years precisely to avoid erroneous deprivation. The more of these due process protections that are eliminated, the more likely there is to be an erroneous deprivation. And, here, the analysis is simple because the PREP Act did not just remove some of these due process protections or even most of them, it removed all of them. The PREP Act simply eliminated all of them and replaced them with their antithesis—a program that offers none of the due process protections Plaintiffs otherwise would have had and instead assures that they will be erroneously deprived of compensation.

155. In sum, Plaintiffs have identified myriad flaws which, taken together, demonstrate the government's disregard of basic due process protections and which do more than create a mere risk of erroneous deprivation; instead, they assure, by design, an unconstitutional outcome.

E. Government's Interest

156. Third, striking down the PREP Act leans in the government's favor. In considering this factor, courts consider, among other things, "the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." *Mathews*, 424 U.S. at 335.

157. Here, striking down the PREP Act to restore pre-existing procedural safeguards will impose no additional financial burden on the federal government. In fact, it will have the opposite effect because the government will no longer need to administer CICIP or pay out any benefits to claimants therein. Claimants could instead seek compensation under appropriate due process safeguards, as they could for centuries prior, in court against the private parties that earned billions of dollars (mostly taxpayer money) selling the products (developed with billions of dollars of taxpayer money) which caused their harm.

158. If this Court declares the PREP Act unconstitutional, this would eliminate CICIP claims and decrease the administrative burden on Defendants. Claimants could presumably pursue relief, in a court of competent jurisdiction, from those who manufactured, distributed, and/or administered the COVID-19 vaccines.

F. Supreme Court Precedent Regarding Compensation Programs

159. The Supreme Court has upheld legislative programs that modify common law rights and provide alternative compensation schemes. *See, e.g., New York Central Railroad Co. v. White*, 243 U.S. 188, 202 (1917) (stating that the no-fault worker's compensation system was a "just settlement" of the problem the legislature sought to address); *Duke Power Co. v. Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 88 (1978) (stating that the Price-Anderson Act

provided a “reasonably just substitute” for common-law or state law remedies for injuries related to nuclear accidents).

160. However, legislative bodies do not possess limitless power to abrogate common-law rights:

I do not understand the Court to suggest that rights of property are to be defined solely by state law, or that there is no federal constitutional barrier to the abrogation of common-law rights by Congress or a state government. The constitutional terms “life, liberty, and property” do not derive their meaning solely from the provisions of positive law. They have a normative dimension as well, establishing a sphere of private autonomy which government is bound to respect. Quite serious constitutional questions might be raised if a legislature attempted to abolish certain categories of common-law rights in some general way. Indeed, our cases demonstrate that there are limits on governmental authority to abolish “core” common-law rights, including rights against trespass, at least without a compelling showing of necessity or a provision for a reasonable alternative remedy.

Pruneyard Shopping Ctr. v. Robins, 447 U.S. 74, 93 (1980) (Marshall, J., concurring); *see also* *Fein v. Permanente Medical Group*, 474 U.S. 892, 894-895 (1985) (White, J., dissenting) (“Whether due process requires a legislatively enacted compensation scheme to be a quid pro quo for the common-law or state-law remedy it replaces, and if so, how adequate it must be, thus appears to be an issue unresolved by this Court, and one which is dividing the appellate and highest courts of several States.”).

161. By prohibiting judicial relief except in certain extremely limited circumstances (none of which are available to Plaintiffs), the PREP Act has extinguished Plaintiffs’ tort causes of action under state law and has instead implemented a convoluted, underfunded, and opaque process that is wholly inadequate for Plaintiffs to seek compensation for their injuries. Thus, the government has failed to provide a “reasonably just substitute” or “reasonable alternative remedy” for taking Plaintiffs’ state or common-law rights to recover damages for their injuries.

162. CACP, established by the PREP Act, violates Plaintiffs' rights under the Fifth Amendment by eliminating rights that otherwise exist under state law and instead directs Plaintiffs' claims through CACP, which fails to provide essential due process protections.

163. Accordingly, CACP directly and proximately deprives Plaintiffs of their procedural due process rights under the Fifth Amendment. CACP is unconstitutional on its face and as applied to Plaintiffs, and Plaintiffs are entitled to a declaratory judgment and the issuance of an injunction.

COUNT III

DUE PROCESS CLAUSE OF THE FIFTH AMENDMENT – SUBSTANTIVE DUE PROCESS VIOLATION

164. Plaintiffs reincorporate the preceding paragraphs as if fully written herein.

165. The Due Process Clause guarantees more than fair process; it also includes a substantive component that “provides heightened protection against government interference with certain fundamental rights and liberty interests.” *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (quotation marks omitted). The right to pursue redress for injuries or wrongs is a bedrock principle of America's legal system. In some circumstances, the Supreme Court has upheld legislation that modifies or abrogates a common law right to a tort claim, provided that the legislature has replaced the extinguished right with a just and reasonable substitute. *See, e.g., Duke Power*, 438 U.S. at 88 (stating that the Price-Anderson Act provided a “reasonably just substitute” for common-law or state law remedies for injuries related to nuclear accidents); *New York Central Railroad Co. v. White*, 243 U.S. 188, 202 (1917) (holding that New York's no-fault worker's compensation system was a “just settlement” for the common law tort claim the system modified).

A. Failure to Provide a Reasonably Just Substitute

166. Here, the fundamental rights and liberty interests involved are Plaintiffs' right to redress their grievances by bringing common law claims against the manufacturers of the products that grievously harmed them. In place of that right, the government has created CICIP, which is constitutionally insufficient. While other replacement schemes have been held to pass as constitutional, this was because they were: (i) adequately funded, and (ii) incentivized responsible behavior. *See Duke Power*, 438 U.S. at 66; *White*, 243 U.S. at 194.

167. The opposite is true of CICIP. CICIP is a severely underfunded program and rife with perverse incentives. CICIP denies 98% of claims. In point of fact, the average payout for COVID-19 CICIP claims is \$3,743.18, and less than 1% of CICIP claimants filing claims related to COVID-19 countermeasures have received compensation. This result is no surprise given HRSA's paltry 2023 budget of \$7 million dollars. Because of the number of claims filed, there is simply no way those harmed by a COVID-19 vaccine could ever receive fair redress for the harms caused. If the current total of 12,854 claimants were all paid from the \$7 million budget, each would be able to receive a maximum of \$544.58. And what little funds are allocated to CICIP are extracted from the public, providing no deterrent for risky and socially destructive behaviors by the actors who caused the harms.

168. In short, CICIP violates substantive due process because its compensation scheme is not a "just and reasonable substitute" for the state tort claims that it extinguished. Because of severe underfunding and due to its shockingly low damage caps, amongst other CICIP Deprivations, it is guaranteed that catastrophically injured citizens are prohibited from receiving

just compensation for the injuries the federal government’s policies caused.³⁶

169. In sum, the provisions of the PREP Act pertaining to CICIP, including but not limited to 42 U.S.C. § 247d-6d, extinguished Plaintiffs’ tort causes of action under state law. CICIP’s provisions are arbitrary and capricious because, both facially and as applied to Plaintiffs, the program fails to provide a “reasonably just substitute” or “reasonable alternative remedy” for eliminating Plaintiffs’ fundamental right to recover damages for their injuries. As delineated above, CICIP decides claims off the record, without meaningful notice to claimants and opportunity to be heard or appeal errant bureaucratic decisions. Plaintiffs cannot review the government’s evidence, confront or question the government’s experts or witnesses, present their case in court or in any formal hearing. These and the other CICIP Deprivations, along with CICIP’s 98% denial rate and *de minimis* compensation show that, in effect, CICIP extinguishes Plaintiffs’ legal claims for their injuries in exchange for no compensation.

170. Consequently, because the PREP Act interferes with Plaintiffs’ fundamental rights and liberty interests—insofar as it substitutes their right to redress their grievances before a jury

³⁶ CICIP also extinguishes state constitutional rights to a just alternative remedy. Where state legislatures interfere with a common law right, even modifications to common law causes of action are regularly struck down in state courts where a fair alternative is not supplied. *See, e.g., Mello v. Big Y Foods, Inc.*, 826 A.2d 1117, 1124-25 (Conn. 2003) (“It is settled law that [the Connecticut Constitution] restricts the power of the legislature to abolish a legal right existing at common law prior to 1818 without also establishing a reasonable alternative to the enforcement of that right”); *Tillman v. Goodpasture*, 485 P.3d 656, 667 (Kan. 2021) (observing that, while the legislature can modify the common law right, it must provide “an adequate substitute remedy for the right infringed or abolished”); *Virilar v. Puente*, 664 S.W.3d 53 (Tex. 2022), *rehg denied*, 2023 Tex. LEXIS 400 (holding that legislation withdrawing common-law remedies is valid under the Texas Constitution only if “it is reasonable in substituting other remedies” or “it is a reasonable exercise of the police power in the interest of the general welfare”); *Busch v. McLinnis Waste Sys.*, 468 P.3d 419 (Or. 2020) (holding statutory damages cap unconstitutional under Oregon Constitution and, therefore, void); *Waite v. Utah Labor Comm’n*, 416 P.3d 635, 642 (Utah 2017) (holding Utah’s Constitution requires “an effective and reasonable alternative remedy” where a common law right is abrogated). *See also Fein v. Permanente Med. Group*, 474 U.S. 892, 893-95 (1985) (White, J., dissenting from dismissal of appeal) (observing the open question whether due process forbids states from enacting damage caps without providing a *quid pro quo* to persons whose claims are capped).

with an egregiously insufficient, secretive, administrative process replete with arbitrary rules—the PREP Act is violative of Plaintiffs’ substantive due process rights and the Court should enter summary judgment in favor of Plaintiffs.

171. CICP is unconstitutional on its face and as applied to Plaintiffs, and Plaintiffs are entitled to a declaratory judgment and the issuance of an injunction.

PRAYER FOR RELIEF

1. **DECLARE** that the provisions of the PREP Act which create the scheme providing liability protection and a compensation process for COVID-19 vaccines, including but not limited to 42 U.S.C. §§ 247d-6d and 247d-6e, are unconstitutional under the Fifth Amendment both on their face and as applied to Plaintiffs;

2. **AWARD** Plaintiffs their costs and attorneys’ fees under 28 U.S.C. § 2412 and any other applicable authority, and any other such relief this Court deems just and proper.

Dated: March 12, 2024

Respectfully submitted,

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*Admitted *pro vac vice*.

VERIFICATION

I, Michelle Zimmerman, a citizen of the United States and of the state of Washington, have read the foregoing Third Amended Verified Complaint and know the contents thereof as to myself in paragraphs 7, 20, and 67-81, that the same are true to my own knowledge, and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on March 11, 2024, in Seattle, Washington.



Michelle Zimmerman

VERIFICATION

I, Carolina Bourque, a citizen of the United States and of the state of Louisiana, have read the foregoing Third Amended Verified Compliant and know the contents thereof as to myself in paragraphs 4, 17, and 25-36, that the same are true to my own knowledge, and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on March 11, 2024, in Youngsville, Louisiana.



Carolina Bourque

VERIFICATION

I, Christopher Cody Flint, a citizen of the United States and of the state of Mississippi, have read the foregoing Third Amended Verified Complaint and know the contents thereof as to myself in paragraphs 6, 19, and 57-66, that the same are true to my own knowledge, and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on March 11, 2024, in Boyle, Mississippi.



Christopher Cody Flint

VERIFICATION

I, Jessica Krogmeier, a citizen of the United States and of the state of Iowa, have read the foregoing Third Amended Verified Complaint and know the contents thereof as to myself in paragraphs 8, 21, and 82-95, that the same are true to my own knowledge, and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on March 11, 2024, in Donnellson, Iowa.



Jessica Krogmeier

VERIFICATION

I, Emma Burkey, a citizen of the United States and of the state of Nevada, have read the foregoing Third Amended Verified Complaint and know the contents thereof as to myself in paragraphs 5, 18, and 37-56, that the same are true to my own knowledge, and as to all other matters on information and belief and I believe them to be true.

I verify under penalty of perjury that the foregoing is true and correct.

Executed on March 11, 2024, in Henderson, Nevada.



Emma Burkey